CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-528

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Consult review for HFD-550

27 February 2003

NDA:	21-528
Name of Drug:	Ketorolac Tromethamine ophthalmic Solution 0.4%
Review Number:	1
Submission Date:	August 6, 2002
Applicant:	Allergan
Name of Reviewer:	Vinayak Pawar
Conclusion:	The application is recommended for approval from microbiological standpoint.

Product Quality Microbiology Data Sheet

A. 1. **NDA:** 21-528

2. **REVIEW NUMBER:** 1

3. **REVIEW DATE:** 27 February 2003

4. **APPLICANT/SPONSOR:**

Name:	Allergan
Representative:	Elizabeth Bancroft
Telephone:	(714)-246-4391

5. **MANUFACTURING SITE:** Waco, Texas

6. **DRUG PRODUCT NAME:**
Proprietary: No proposed trade name yet.
Non-proprietary: Ketorolac Tromethamine Ophthalmic Solution 0.4%
Drug Priority Classification: Standard

7. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 0.4% Ophthalmic preparation

8. **METHOD (S) OF STERILIZATION:** Aseptic

9. **PHARMACOLOGICAL CATEGORY:** Occular pain

B. 1. **DOCUMENT/LETTER DATE:** August 6, 2002
2. **RECEIPT DATE:** August 9, 2002
3. **CONSULT DATE:** August 14, 2002
4. **DATE OF AMENDMENTS:** NA
5. **ASSIGNED FOR REVIEW:** August 23, 2002
6. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The consult requests review of original NDA 21-528 for reformulation of Allergan's current product ACULAR 0.5% to a 0.4% concentration. The sponsor has not provided a trade name for this new formulation. The application has been submitted electronically. A paper review copy was also submitted for microbiology review in two volumes (1 & 10).

Executive Summary

I. Recommendations

A. Recommendation on Approvability –

The new NDA application submitted for the reformulation of a previously approved product "ACULAR" (ketorolac tromethamine) and will be manufactured, packaged and labeled in the same manner. The aseptic manufacturing process consisting of [redacted] system remains the same as previously approved and assures adequate safety from microbiological standpoint.

B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable
NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology
Ketorolac tromethamine at 0.4% w/v will be the active ingredient whereas benzalkonium chloride as the preservative, octoxynol-40 as the stabilizer and other ingredients will remain the same. The product is : [redacted]
multiple dose 10 mL eye drop bottles in 5 [redacted] volumes (FIG. 1). The product is manufactured using the same previously approved processes as described in NDAs 19-700 and 20-811.

B. Brief Description of Microbiology Deficiencies
None

C. Assessment of Risk Due to Microbiology Deficiencies-
NA

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Vinayak Pawar/27 February 2003
Peter H. Cooney/

C. CC Block
cc:
Original NDA 21-528
HFD-550/Division File/ Raphael Rodriguez

Number of Pages Redacted 9

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/s/

Vinayak Pawar
3/7/03 11:22:04 AM
MICROBIOLOGIST

Peter Cooney
3/7/03 12:12:36 PM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL